

1 ENERGY AND ENVIRONMENT CABINET

2 Department for Environmental Protection

3 Division of Water

4 (Amendment)

5 401 KAR 8:040. Laboratory certification.

6 RELATES TO: KRS 224.10-100, 224.10-110, 40 C.F.R. 141.28, 141 Subpart C, Appendix  
7 A, 141.201-211, Appendix A, B, EO 2009-538 [~~2008-507, 2008-531~~]

8 STATUTORY AUTHORITY: KRS 224.10-100(28), 224.10-110(2), 40 C.F.R. 141.28, 42  
9 U.S.C. 300f-300j-26, EO 2009-538

10 NECESSITY, FUNCTION, AND CONFORMITY: KRS Chapter 224.10-110(2) authorizes  
11 the cabinet to enforce the administrative regulations promulgated by the secretary for the  
12 regulation and control of the purification of water for public and semipublic use. EO 2009-538,  
13 effective June 12, 2009, establishes [~~2008-507 and 2008-531, effective June 16, 2008, abolish~~  
14 ~~the Environmental and Public Protection Cabinet and establish~~] the new Energy and  
15 Environment Cabinet. This administrative regulation establishes procedures for certification of  
16 commercial or water system laboratories to test for drinking water contaminants [~~various~~  
17 ~~analysis categories or constituents within an analysis category~~].

18 Section 1. Laboratory Certification. (1) The U.S. Environmental Protection Agency or the  
19 cabinet shall evaluate a public water system laboratory or a commercial laboratory that performs  
20 drinking water analysis for a public water system for certification.

21 (2) Contracting by the cabinet with a third party to conduct laboratory evaluations and make

1 recommendations to the cabinet regarding certification shall be in accordance with the Manual  
2 for the Certification of Laboratories Analyzing Drinking Water; Criteria and Procedures Quality  
3 Assurance [~~and Kentucky Drinking Water Laboratory Certification Program Manual~~].

4 (3)(a) Certification may be for one (1) or more analysis categories or for a single drinking  
5 water contaminant [~~constituent~~] within an analysis category.

6 (b) Each analysis category shall require a different certification, but qualification for  
7 different certifications may be evaluated during one (1) audit [~~inspection~~].

8 Section 2. Application. (1) An initial certification request may be made at any point during  
9 the calendar year.

10 (2) A laboratory seeking certification shall submit a written request for certification to the  
11 cabinet. The request shall include:

12 (a) A statement of the analysis category or drinking water contaminant for which  
13 certification is requested;

14 (b) A list of the analytic methods for each analysis [~~analyst~~] for which certification is  
15 requested; [~~and~~]

16 (c) Payment of the fee established in 401 KAR 8:050, Section 2(5) for the certification  
17 requested; and

18 (d) Completion of a Performance Evaluation (PE) study for each analysis category or  
19 drinking water contaminant for which certification is requested.

20 (3) The cabinet may request other information necessary to determine eligibility for  
21 certification as described in the Manual for the Certification of Laboratories Analyzing Drinking  
22 Water; Criteria and Procedures Quality Assurance [~~and Kentucky Drinking Water Laboratory~~  
23 ~~Certification Program Manual~~].

1 (4)(a) An applicant who has been de-certified in accordance with the Manual for the  
2 Certification of Laboratories Analyzing Drinking Water; Criteria and Procedures Quality  
3 Assurance for an analysis category or drinking water contaminant may request recertification in  
4 accordance with Section 2 of this administrative regulation.

5 (b) The applicant for recertification shall pay the fee established in 401 KAR 8:050, Section  
6 2(4).

7 Section 3. Public Water System Laboratory. (1) A Public water system may establish a  
8 laboratory. Each laboratory shall be certified annually.

9 (2) Failure to achieve or maintain annual certification shall not relieve the public water  
10 system of the responsibility to report results of the required analyses from a certified laboratory.

11 Section 4. Requirements. Maintenance of certification shall require the following:

12 (1) Analysis. Analysis shall be performed in accordance with the appropriate approved  
13 method established in 40 C.F.R. Subpart C, including Appendix A~~[, effective June 3, 2008];~~

14 (2) Submission of analysis results. ~~[Except as provided in subsection (5) of this section,]~~ The  
15 result of each analysis performed in a certified laboratory by or for a public water system shall be  
16 submitted to the cabinet by the tenth day of the month following the compliance ~~[testing]~~ period  
17 for which the analysis was performed and shall be submitted to the public water system as soon  
18 as possible. The public water system shall be responsible for this reporting requirement; and

19 (3) Performance evaluation sample. A Performance evaluation (PE) sample shall be analyzed  
20 for each analysis category or drinking water contaminant for which certification is requested and  
21 the results shall be submitted to the cabinet at times specified in the Manual for the Certification  
22 of Laboratories Analyzing Drinking Water; Criteria and Procedures Quality Assurance~~[, and~~  
23 ~~Kentucky Drinking Water Laboratory Certification Program Manual]~~ not to exceed twice a year,

1 unless additional results shall be required in accordance with the Manual for the Certification of  
2 Laboratories Analyzing Drinking Water; Criteria and Procedures Quality Assurance [~~and~~  
3 ~~Kentucky Drinking Water Laboratory Certification Program Manual~~].

4 Section 5. Deviations. (1) Deviation from accepted practice specified in the Manual for the  
5 Certification of Laboratories Analyzing Drinking Water; Criteria and Procedures Quality  
6 Assurance [~~and Kentucky Drinking Water Laboratory Certification Program Manual~~], listed on a  
7 report resulting from an on-site inspection, shall be corrected.

8 (2) A written explanation of the deviation and action taken to correct it shall be submitted to  
9 the cabinet within thirty (30) days of the issuance of the inspection report.

10 Section 6. Violations. (1) A laboratory shall report any violation of a maximum contaminant  
11 level or other violation requiring Tier 1 public notification pursuant to 401 KAR 8:070 to the  
12 public water system and the cabinet within twenty-four (24) hours of sample analysis, in  
13 accordance with 40 C.F.R. 141.201-141.211, Appendix A and Appendix B[~~, effective July 1,~~  
14 ~~2007~~].

15 (2) A public water system shall begin check sampling within twenty-four (24) hours of  
16 notification of a violation.

17 (6) Emergency provision. A laboratory [~~Laboratories~~] shall make provisions to receive and  
18 test samples twenty-four (24) hours a day during an emergency.

19 Section 7. Right of Entry. A certified laboratory shall permit the cabinet to conduct on-site  
20 surveys during normal business hours, without prior notification.

21 Section 8. Revocation of certification and downgrading of certification shall be in accordance  
22 with the procedures established in the Manual for the Certification of Laboratories Analyzing  
23 Drinking Water; Criteria and Procedures Quality Assurance [~~and Kentucky Driving Water~~

~~Laboratory Certification Program Manual].~~

(1) A laboratory that has been notified of a change of certification shall, within seventy-two (72) hours, notify the public water systems that the laboratory serves of the change in certification status and any impact that change could have on the public water system.

(2) A laboratory may provide monitoring reports by sub-contracting with a laboratory that is certified by the cabinet. ~~[contracting with a certified laboratory that shall comply with the Manual for the Certification of Laboratories Analyzing Drinking Water; Criteria and Procedures Quality Assurance and Kentucky Drinking Water Laboratory Certification Program Manual.]~~

Section 9. Recognition of an Out-of-state Laboratory. (1) The cabinet shall recognize a laboratory located outside Kentucky upon submission of proof by the laboratory that it is certified by the Environmental Protection Agency ~~[certification]~~, or by a state having primary enforcement responsibility for the provisions of the Safe Drinking Water Act, 42 U.S.C. 300f through 300j-26, or that is certified pursuant to the Safe Drinking Water Act, 42 U.S.C. 300f through 300j-26, requirements.

(2) A water system located in Kentucky that has entered into a contract with a certified out-of-state laboratory shall comply with time intervals and capabilities established in the Manual for the Certification of Laboratories Analyzing Drinking Water; Criteria and Procedures Quality Assurance ~~[and Kentucky Drinking Water Laboratory Certification Program Manual].~~

(3) If on-site inspection shall be conducted for certification of an out-of-state laboratory, the laboratory shall bear the cost.

Section 10. Incorporation by Reference. (1) ~~[The following material is incorporated by reference:~~

~~(a)]~~"Manual for the Certification of Laboratories Analyzing Drinking Water; Criteria and

1 Procedures Quality Assurance; Fifth Edition, January 2005", Publication EPA 815-R-05-004 is  
2 incorporated by reference.[-; and

3 ~~(b) "Kentucky Drinking Water Laboratory Certification Program Manual", December 2008.]~~

4 (2) This material may be inspected, copied, or obtained, subject to applicable copyright law,  
5 at the Kentucky Division of Water, 200 Fair Oaks Lane, Frankfort, Kentucky, Monday through  
6 Friday, 8 a.m. to 4:30 p.m.

401 KAR 8:040 “Laboratory Certification” approved for promulgation:

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Date

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Leonard K. Peters, Secretary  
Energy and Environment Cabinet

**PUBLIC HEARING AND PUBLIC COMMENT PERIOD:** A public hearing on this administrative regulation shall be held on November 23, 2009, at 4:00 P.M. (Eastern Time) at 300 Fair Oaks Lane, Conference Room 301D, Frankfort, Kentucky. Individuals interested in being heard at this hearing shall notify this agency in writing by November 16, 2009, five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted until November 30, 2009. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

**CONTACT PERSON:** Abigail Powell, Regulations Coordinator  
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## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #: 401 KAR 8:040

Contact Person: Sandy Gruzesky, Director

**(1) Provide a brief summary of:**

- (a) What this administrative regulation does:** This administrative regulation provides procedures for the certification of laboratories performing analysis for public and semipublic water systems.
- (b) The necessity of this administrative regulation:** This administrative regulation is necessary to assure that Kentucky has an adequate number of certified laboratories to conduct analysis for public water systems.
- (c) How this administrative regulation conforms to the content of the authorizing statutes:** KRS 224.10-110 authorizes the cabinet to enforce regulations for the purification of drinking water for public and semipublic use. 40 C.F.R. 142.10(3) requires states to have a program for laboratory certification in order to obtain primary enforcement responsibility for the Safe Drinking Water Act.
- (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:** This administrative regulation allows the cabinet to certify laboratories to carry out necessary analysis of drinking water.

**(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:**

- (a) How the amendment will change this existing administrative regulation:** This administrative regulation is being amended in order to adopt the latest analytical techniques approved by the U. S. Environmental Protection Agency, to delete the Kentucky manual and to clarify the application and certification process. The Kentucky Drinking Water Laboratory Certification Program manual is an internal manual describing administrative procedures and does not provide useful information to the regulated public.
- (b) The necessity of the amendment to this administrative regulation:** The amendment to this administrative regulation will allow certified laboratories to use the most recently approved analytical techniques.
- (c) How the amendment conforms to the content of the authorizing statutes:** KRS 224.10-110 authorizes the cabinet to enforce regulations for the purification of drinking water for public and semipublic use. 40 C.F.R. 142.10(3) requires states to have a program for laboratory certification in order to obtain primary enforcement responsibility for the Safe Drinking Water Act. The amendments to this administrative regulation allow certified laboratories to use the latest approved analytical techniques.
- (d) How the amendment will assist in the effective administration of the statutes:** The ability to use the latest approved analytical techniques will allow a public water system and its laboratory to tailor monitoring to achieve the most cost effective means of compliance with monitoring requirements.

- (3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:** Currently, there are 43 certified microbiology laboratories and 23 certified chemistry laboratories in Kentucky. Nineteen

microbiology and four chemistry laboratories are municipally owned. Outside Kentucky, there is one certified microbiology laboratory and fifty-two certified chemistry laboratories. These laboratories serve 479 public, 55 semipublic, and 7 bottled water systems in Kentucky.

**(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:**

- (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:** The amendment to this regulation will give a certified laboratory increased flexibility in pursuing techniques or methods to monitor drinking water.
- (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):** The amendments to this administrative regulation will not increase costs.
- (c) As a result of compliance, what benefits will accrue to the entities identified in question (3):** A certified laboratory will have a wider selection of methods for testing drinking water from which to choose. This could reduce costs to public water systems.

**(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:**

- (a) Initially:** No additional cost is anticipated.
- (b) On a continuing basis:** No additional cost is anticipated.

**(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation?** This administrative regulation is funded by a combination of state general funds, fees, and federal funds provided to support the enforcement of the Safe Drinking Water Act.

**(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:** This proposed amendment will not require an increase in laboratory certification fees or an increase in funding.

**(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees:** This proposed amendment does not directly or indirectly establish or increase fees.

**(9) TIERING: Is tiering applied? (Explain why or why not)**

Yes. A laboratory may be certified for a single analysis category, a group of analysis categories, or for all analysis categories that are monitored in drinking water.

## FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation #: 401 KAR 8:040

Contact Person: Sandy Gruzesky, Director

- 1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)?**

Yes   X   No       

If yes, complete questions 2-4.

- 2. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?**

This administrative regulation applies to certified laboratories that do analysis for contaminants in public and semipublic water systems. Public water systems are often owned by city governments or organized under county governments. Other entities, such as associations, privately-owned or investor-owned entities, may have a water system.

- 3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.**

KRS 224.10-110 authorizes the cabinet to enforce regulations for the purification of drinking water for public and semipublic use. 40 C.F.R. 142.10(3) requires that the cabinet have a laboratory certification program as a condition to having primary enforcement responsibility for the Safe Drinking Water Act.

- 4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.**

**(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?** This administrative regulation will not generate any revenue in the first year.

**(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?** This administrative regulation will not generate any revenue in subsequent years.

**(c) How much will it cost to administer this program for the first year?** No additional costs are anticipated.

**(d) How much will it cost to administer this program for subsequent years?** No additional costs are anticipated.

**Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.**

**Revenues (+/-):**

**Expenditures (+/-):**

**Other Explanation:**

## FEDERAL MANDATE ANALYSIS COMPARISON

Administrative Regulation#: 401 KAR 8:040

Contact Person: Sandy Gruzesky, Director

**1. Federal statute or regulation constituting the federal mandate.**

40 C.F.R. 142.10(3)

**2. State compliance standards.**

KRS 224.10-110

**3. Minimum or uniform standards contained in the federal mandate.**

40 C.F.R. 142.10(3) requires states to have a laboratory certification program as a condition to receiving primary enforcement responsibility for the Safe Drinking Water Act.

**4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements than those required by the federal mandate?**

The amendment to this regulation does not impose stricter, additional, or different requirements from the federal mandate. These requirements are not changing in the proposed amendment.

**5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.**

Not applicable.